DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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DEC 18 1998

WARNING LETTER

VIA FEDERAL EXPRESS

Ref:OC:I1-1809

Mr. M. Riel
President
Dentek-Lasersystems Produktions Ges.m.b.H.
Gasselberg 53-54
A-8564 Gaisfeld
Austria

Dear Mr. Riel:

This letter is written to advise you of noncompliances with the Federal laser product performance standard encountered during review of the report on the Dentek LD 15 dental laser system, dated April 29, 1998, Accession Number 9810588. Dental lasers are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

1. 21 CFR 1040.11(a)(2). Neither the Dentek LD 15 Operator's Manual nor the Technical Manual includes adequate calibration procedures, required to be supplied with each Class III and IV medical laser product. Although we would not object to your inclusion of statements such as you have to the effect that only authorized representatives of Dentek may perform the procedure and that user recalibration would invalidate the warranty, the requirement is clear that the instructions must be supplied to the purchaser.

You will recognize that this requirement is virtually identical in the IEC 825 standard.

2. 21 CFR 1010.2. The Dentek LD 15 laser lacks a certification label stating that the product complies with the Federal laser product performance standard.

3. 21 CFR 1010.3. The Dentek LD 15 laser lacks an identification label giving the manufacturing location and date of manufacture.

Section 538(a) of the Act, Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any manufacturer from certifying or introducing into commerce laser products which do not comply with the standard.

This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports. Failure to respond to this letter may be considered to be in violation of section 538(a)(4) of the Act.

This letter is not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance programs. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration (FDA). If the causes are determined to be systemic problems you must promptly initiate permanent corrective actions. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. In cases where a foreign manufacturer fails to respond, penalties may be imposed upon importers.

You must respond in writing within 15 working days of receipt of this letter to one of the options listed below. In your response you must also provide the number of the referenced products which have been produced and the number of such products that have left the place of manufacture. In addition, if the product distribution was confined to specific geographical areas of the United States, please specify those areas.

1. Refutation - You may submit your views and evidence to establish that the alleged noncompliances do not exist.

2. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31).

3. Purchaser Notification and Corrective Action - If you neither refute the noncompliance nor request an exemption, then you must: (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and
(b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.

a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.

b. Corrective Action Plan - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required to proceed with interim notification to affected persons as required by 21 CFR 1003.11(c) and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

When you have completed any production changes necessary to assure compliance of future units and you have submitted the required reports and report supplements, you may resume introduction of these products into commerce.

Your response should be sent to: General Surgery Devices Branch, Division of Enforcement I (HFZ-323), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850 USA. If you have further questions on these requirements, please contact Ms. Cory Tylka of the General Surgery Devices Branch at phone: 301-594-4595, ext. 170, or FAX: 301-594-4636.

Sincerely yours,

Reva J Melton

for Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

CC: Mr. Wolfgang Ninaus
Director of Engineering
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Mr. Donald a la Point
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